K023152

DEC 17 2002

510 (k) Summary
Safety and Effectiveness

This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: **Address:**	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, CA 90045
Telephone Number: **Facsimile Number:**	(310) 645-8200 (310) 645-9999
Contact Person:	Edward M. Levine, Ph.D. Director of Clinical Affairs
Date of Preparation:	December 11, 2002
Device Name: Trade:	IMMULITE® 2000 Allergen-Specific IgE
Catalog Number:	L2KUN6 (600 tests)
CFR:	866.5750
Common:	Allergens for the determination of Allergen-Specific IgE in human serum.
Classification:	Class II device, 82-DHB (21 CFR 866.5750)
Panel:	Immunology
CLIA Complexity Category:	Moderate, based on previous classification of analogous tests.
Manufacturer:	Diagnostic Products Corporation (DPC) 5700 West 96th Street Los Angeles, CA 90045-5597
Establishment Registration #:	DPC's establishment Registration No. is 2017183

FDA/CDRH/OSE/PMO
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Description of Device: IMMULITE® 2000 Allergen-Specific IgE is a solid-phase, two-step, chemiluminescent immunoassay for use with the IMMULITE® 2000 Automated Analyzer.

Intended Use of the Device: The IMMULITE® 2000 Allergen-Specific IgE assay is intended for *in-vitro* use with the IMMULITE® 2000 Automated Analyzer - for the quantitative measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders.

Technology:

IMMULITE 2000 Allergen-Specific IgE is a solid-phase, two-step, chemiluminescent immunoassay that exploits liquid phase kinetics in a bead format. The allergens are covalently bound to a soluble polymer/co-polymer matrix, which in turn is labeled with a ligand. The use of an amino acid co-polymer amplifies the amount of allergen that the matrix can support.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light. The emission of light, as measured by the luminometer, is related to the presence of allergen-specific IgE in the sample.

Performance Data:

Calibration Range: 0.1 – 100 kU/L (WHO 2nd IRP 75/502).

Analytical Sensitivity: 0.1 kU/L.

Linearity: Average recovery for three serially diluted samples were 103%, 104%, and 104%, respectively.

Precision: Samples were assayed in duplicate over the course of 20 days, two runs per day, for a total of 40 runs and 80 replicates. The average intraassay CV for the 22 specimens included in the precision study was 5.9%, and the total CV 7%.

Specificity: The antibodies are highly specific for human IgE and exhibit no crossreactivity to other human Immunoglobulin classes.

Bilirubin: Presence of conjugated and unconjugated bilirubin in concentrations up to 200 mg/L has no effect on results, within the precision of the assay.

Hemolysis: Presence of hemoglobin in concentrations up to 500 mg/dL has no effect on results, within the precision of the assay.

Lipemia: Presence of triglycerides in concentrations up to 3,000 mg/dL has no effect on results, within the precision of the assay.

Performance Equivalence:

Diagnostic Products Corporation asserts the IMMULITE 2000 Allergen-Specific IgE produce substantially equivalent results to the AlaSTAT Microplate Allergen-Specific IgE, a FDA cleared immunoassay kit.

Method Comparison:

The IMMULITE 2000 Allergen-Specific IgE assay was compared to IMMULITE 2000 AlaSTAT Microplate Allergen-Specific IgE on 7,520 serum samples.

IMMULITE 2000	AlaSTAT Microplate 0	1	2	3	4	5	6
6			1	3	30	43	303
5				13	75	33	35
4			3	181	169	26	10
3		2	297	608	47	2	2
2	16	230	887	89	1		
1	115	171	90	3			
0	3,909	116	9	1			

Total Agreement: 97%
Relative Sensitivity: 96%
Relative Specificity: 97%
Total Identical: 81%
Class 1 Identical: 99%
Class 2 Identical: 100%

Means of Class Scores:
1.29 (AlaSTAT)
1.37 (IML 2000)

The same data was analyzed in a regression analysis with the following results:

IMMULITE 2000 = 1.00 × Microplate + 0.87

r = 0.94

Means:
8.57 kU/L (AlaSTAT)
9.48 kU/L (IMMULITE 2000)

Conclusion:

The data presented in this summary of safety and effectiveness is the data that the Food and Drug Administration used in granting DPC substantial equivalence for IMMULITE® 2000 Allergen-Specific IgE.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 17 2002

Edward M. Levine, Ph.D.
Director of Clinical Affairs
Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, CA 90045-5597

Re: k023152
Trade/Device Name: Immulite® 2000 Allergen-Specific IgE
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RAST) immunological test system
Regulatory Class: Class II
Product Code: DHB
Dated: November 22, 2002
Received: November 25, 2002

Dear Dr. Levine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023152
Device Name: IMMULITE® 2000 Allergen-Specific IgE

Indications For Use: The IMMULITE® 2000 Allergen-Specific IgE assay is intended for *in vitro* diagnostic use with the IMMULITE® 2000 Analyzer – for the quantitative measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓ Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use

(Optional Format 1-2-96)

J P Reeves for J. Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023152